REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Claims 59, 60, 63 and 64 are requested to be cancelled.

Claims 1,4, 8, 9, 10, 11, 16, 21, 24, 29, 30, 36 and 41 are currently being amended.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

After amending the claims as set forth above, claims 1-41, 57-58 and 61-62 are now pending in this application.

In the action of April 4, 2005, the Examiner rejected claims 1-41 and 57-64 under 35 U.S.C. §§ 102(e) and (g) as being anticipated by U.S. Patent No. 6,432,437, issued to Hubbard (the '437 patent). The Examiner also rejected claims 1-41 under 35 U.S.C. § 102(f) as being anticipated by the '437 patent. Lastly, the Examiner rejected all of the claims under 35 U.S.C. § 101 as claiming the same invention as that of claims 1-30 of the '437 patent.

In response to the Examiner's rejections, Applicants have amended each of independent claims 1, 4, 8-11, 16, 21, 24, 29, 30, 36 and 41 to describe the polysaccharide gel being used for the carrier as having a viscosity between greater than 200,000 centipoise to about 350,000 centipoise, and claims 59, 60, 63 and 64 have been cancelled. Because all of the other pending claims in this application depend upon one of the currently-amended independent claims, all of the claims in the present application now include this limitation.

Because the use of a gel with a viscosity between greater than 200,000 centipoise and about 350,000 is not taught, disclosed or suggested by the '437 patent, Applicants submit that all

of the Examiner's rejections under 35 U.S.C. §§ 102 and 103 are overcome by these amendments.

U.S. Patent No. 6,432,437, issued to the Assignee of the current application, is directed to a carrier for suspending a particulate ceramic in a tissue augmentation material. The gel for use as part of this carrier is discussed in detail at column 10, line 8-column 11, line 5 of the '437 patent. Importantly, this section explicitly limits viscosity of the material that can be used as the polysaccharide gel:

> The viscosity of the gel can vary from about 20,000 to 200,000 centipoise, preferably about 40,000 to 100,000 centipoise as measured with a Brookfield Viscometer with RU#7 spindle at 16 revolutions per minute (rpm). It has been found that with gel viscosities-below about 20,000 centipoise the particles do not remain in suspension, and with gel viscosities above about 200,000 centipoise, the gel becomes too viscous for convenient mixing. (Col. 10, ll. 22-29).

The '437 patent never hints at using a gel having a viscosity outside of the 20,000-200,000 centipoise range. In fact, the discussion of higher gel viscosities in the quoted passage presents a clear teaching away from the use of >200,000 centipoise viscosity gels. In contrast, the claims as amended in the present application require the presence of a gel having a minimum viscosity of *greater* than 200,000 centipoise. In this light, there is no overlap between the claims in the pending application and what is specifically disclosed in the '437 patent. Because there is no specific teaching in the '437 patent for the use of a gel having a viscosity in the range of greater than 200,000 to about 350,000 centipoise, Applicants submit that all of the Examiner's rejections under the various sections of 35 U.S.C. § 102 are overcome.

In addition to the above, Applicants respectfully traverse the Examiner's double patenting rejection of the pending claims as amended. Both the Manual of Patent Examining Procedure and established case law are clear that a good test for determining whether a double patenting rejection is proper involves determining whether the claim in one of the cases at issue could be literally infringed without literally infringing the claim at issue in the other case. MPEP §

804.01; *In re Vogel*, 422 F.2d 438, 441 (C.C.P.A. 1970). If one claim could be literally infringed without literally infringing the other, then the claims do not define the same invention. *Id.*

In this case, one can go in both directions in finding infringement of one claim but not the other. Looking at claims 1-30 of the '437 patent, all of these claims require the presence of a particulate ceramic. However, the independent claims of the pending application only require the presence of a biomaterial. Given that there are a plethora of non-ceramic biomaterials in existence, one could easily use a non-ceramic biomaterial that meets the limitations of all of the independent claims in the present application that could not infringe any of the claims in the '437 patent.

Looking in the other direction, all of the claims in the pending application now require that the polysaccharide gel have a viscosity in the range of greater than 200,000 to about 250,000 centipoise. However, none of the claims in the '437 patent include such a restriction, instead permitting the use of materials of any viscosity. Once again, it is clearly possible to infringe one group of claims without infringing the others. There are a wide variety of materials with viscosities outside of the claimed range which, if used, could not literally infringe any of the claims in the '437 patent.

In terms of the required viscosity range now required in the pending claims, the Examiner previously stated on Page 4 of the April 4, 2005 Official Action that "[s]ince viscosity is determined by the amount of polysaccharide or the proportion of polysaccharide to water/glycerin, the viscosity values set out in the claims are deemed an inherent property of a composition which has already been set out in Hubbard et al." Applicants respectfully disagree with this position. A measured viscosity depends upon a wide variety of factors, the most important of which is the material itself. As is widely known in the art, different materials can have widely different viscosities. Additionally and as clearly evidenced by the disclosure in the '437 patent itself, a gel can have a viscosity of even below 20,000 centipoise, much less just outside of the +200,000-350,000 centipoise range. This clearly indicates that the viscosity limitation should be given at least some patentable weight.

With regards to the Examiner's comment regarding the proportion of polysaccharide to water/glycerin, this comment is, in fact, evidence that the viscosity is not an inherent property of the gel. The fact that the ratio of these substances affects the gel's ultimate viscosity shows that a manufacturer of a product claimed in either of these cases has a significant degree of control over the viscosity of the resulting gel. As such, it is quite possible to adjust the viscosity of the gel by lowering the amount of polysaccharide relative to the other components of the gel or vice versa. For this reason, it is indeed possible to adjust the viscosity of the gel, by carefully selecting the appropriate polysaccharide, such that the gel would fall outside of the +200,000-250,000 centipoise range of the pending claims while still potentially infringing one or more of the claims in the '437 patent.

For all of the above reasons, Applicants submit that any statutory double patenting rejection of the claims in the pending application based upon claims 1-30 of the '437 patent is overcome.

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 06-1450. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 06-1450. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 06-1450.

Respectfully submitted,

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By

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